UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

YVONNE HARJU, et al. Plaintiffs, v. JOHNSON & JOHNSON, ETHICON, INC., Defendants.	CASE NO. C20-6258 BHS-JRC ORDER ADOPTING IN PART REPORT & RECOMMENDATION

This matter comes before the Court on the Report and Recommendation ("R&R") of the Honorable J. Richard Creatura, United States Magistrate Judge, Dkt. 37, and Plaintiffs Yvonne Harju, Doris Hosking, and Donald Hosking's objections to the R&R, Dkt. 39, and Defendants Johnson & Johnson and Ethicon, Inc.'s objections to the R&R, Dkt. 40.

I. FACTUAL & PROCEDURAL HISTORY

This case arises out of Ms. Harju's surgical implantation of Gynecare TVT-Secur—a prolene mesh implant—to treat her stress urinary incontinence and out of Ms. Hosking's surgical implantation of Gynecare Prosima—another prolene mesh implant—to treat her pelvic organ prolapse. Dkt. 29, ¶¶ 2, 6. Both the TVT-S and Prosima are

medical devices created by Defendants. *Id.* ¶¶ 11–13. Plaintiffs bring claims for violations of the Washington Products Liability Act ("WPLA"), RCW 7.72, *et seq.*, breach of express warranty, breach of implied warranty, fraud, fraudulent concealment, constructive fraud, violations of the Washington Consumer Protection Act ("CPA"), RCW 19.86, *et seq.*, unjust enrichment, and for Mr. Hosking's loss of consortium.

Following Plaintiffs' filing of their Second Amended Complaint, Dkt. 29, Defendants moved to dismiss their claims, Dkt. 30. Judge Creatura issued the instant R&R, recommending that the Court grant in part and deny in part Defendants' motion. Dkt. 37. Specifically, the R&R recommends that the Court dismiss Plaintiffs' claim for unjust enrichment without leave to amend and dismiss their claims for constructive fraud, fraudulent inducement, and breach of implied warranty with leave to amend. The R&R recommends that Defendants' motion to dismiss be denied as to Plaintiffs' remaining claims.

On July 26, 2021, both Plaintiffs and Defendants filed their objections to the R&R. Dkts. 39, 40. Plaintiffs object to the R&R's recommendation to dismiss their claim for unjust enrichment with prejudice. Dkt. 39. Defendants object to the R&R's recommendation to deny their motion to dismiss as to Plaintiffs' claims for manufacturing defect, breach of express warranty, common law fraud, and violations of the CPA. Dkt. 40. On July 29, 2021, the parties responded to the opposing objections. Dkts. 42, 43. On August 17, 2021, Defendants filed a notice of supplemental authority. Dkt. 45.

II. DISCUSSION

A. Standard

The district judge must determine de novo any part of the magistrate judge's disposition that has been properly objected to. The district judge may accept, reject, or modify the recommended disposition; receive further evidence; or return the matter to the magistrate judge with instructions. Fed. R. Civ. P. 72(b)(3).

B. Plaintiffs' Objections

Plaintiffs object to the R&R's recommendation that their unjust enrichment claim be dismissed without leave to amend. Dkt. 39. The R&R concluded that Plaintiffs cannot maintain their claim for unjust enrichment because the WPLA preempts all common law remedies for product-related harms other than fraud, intentionally caused harm, or violations of the CPA. Dkt. 37 at 24–25; *see also* RCW 7.72.010(4); *Wash. Water Power Co. v. Graybar Elec. Co.*, 112 Wn.2d 847, 860 (1989) (en banc) (holding that the WPLA "creates a single cause of action for product-related harms that supplants previously existing common law remedies").

Plaintiffs argue they are entitled to advance separate claims as alternative theories of liability. Dkt. 39 at 3–4. But they do not engage, as Defendants correctly highlight, with the authority which conclusively holds that the WPLA preempts their claim for unjust enrichment. *See* Dkt. 42. "The WPLA is the exclusive remedy for product liability claims" and "supplants all common law claims or actions based on harm caused by a product." *Macias v. Saberhagen Holdings, Inc.*, 175 Wn.2d 402, 409 (2012) (internal citations omitted). While plaintiffs in general are entitled to advance competing theories

of liability, the statutory scheme of the WPLA does not permit Plaintiffs to advance an alternate theory of unjust enrichment here.

The R&R correctly concluded that the WPLA preempts Plaintiffs' claim for unjust enrichment. The R&R is therefore ADOPTED as to this issue.

C. Defendants' Objections

Defendants object to the R&R's recommendation to deny their motion to dismiss as to Plaintiffs' claims for manufacturing defect, breach of express warranty, common law fraud, and violations of the CPA. Dkt. 40. Plaintiffs, in response, argue that the R&R reached the correct conclusions as to these claims and that the Court should adopt the R&R. Dkt. 43. Defendants additionally filed a notice of supplemental authority to support their objections. Dkt. 45.

1. Manufacturing Defect

Defendants first object to the R&R's conclusion that Plaintiffs plausibly alleged a manufacturing defect claim under the WPLA. Dkt. 40 at 5–12. "A design defect is a defect that is present across an entire product line when some aspect of the product is unsafe, while a manufacturing defect is due to factory departure from proper specifications." *Moore v. Harley-Davidson Motor Grp., Inc.*, 158 Wn. App. 407, 425 (2010); *see also Bylsma v. Burger King Corp.*, 176 Wn.2d 555, 559 (2013). The R&R concluded that there is a reasonable inference from the complaint that there was a departure from proper specifications by Defendants in using non-medical grade materials or manufacturing techniques that resulted in sharp product edges. Dkt. 37 at 11. The Court respectfully disagrees with this conclusion.

Defendants argue persuasively that Plaintiffs have failed to plead a plausible manufacturing defect claim because they do not allege how the TVT-S and Prosima implants that were implanted in Ms. Harju and Ms. Hosking, respectively, deviated from their intended designs. Plaintiffs do allege that the TVT-S and Prosima products *in general* were defective due to, among others, the use of non-medical grade material. Dkt. 29, ¶¶ 128–132. These allegations sound in a design defect, not in a manufacturing defect.

Rather than alleging that the products *specific* to Ms. Harju and Ms. Hosking are defective "due to factory departure from proper specifications," *Moore*, 158 Wn. App. at 425, Plaintiffs allege that the mesh implants are dangerous as designed. If, for example, the TVT-S and Prosima products were defective due to inadequate specifications that were not adhered to in the manufacturing of Plaintiffs' products, *see* Dkt. 29, ¶ 128, then the specifications were unsuitable as designed. Plaintiffs' allegations do not support an inference that their specific products departed from proper specifications; rather, Plaintiffs allege that every mesh product was defective.

While not binding on this Court's analysis, the Court does find persuasive that other federal courts from around the country addressing manufacturing defect claims for mesh products have reached this same conclusion. *See, e.g.*, *Drumheller v. Johnson & Johnson*, No. 20-6535, 2021 WL 1853407, at *7–8 (E.D. Pa. May 10, 2021) ("As the gravamen of Ms. Drumheller's complaint is defect in the design of pelvic mesh, we find she fails to plead a manufacturing defect."); *Payton v. Johnson & Johnson*, No. 4:20-cv-00257-JMS-DML, 2021 WL 1923799, at *7 (S.D. Ind. May 13, 2021) ("First, the

Amended Complaint lacks any allegations explaining the intended proper design of the TVT Product. Second, Ms. Payton does not allege facts showing how, in even the most general sense, Ms. Payton's Implant deviated from the intended design of the TVT Product.").

Defendants request that the Court dismiss Plaintiffs' manufacturing defect claim without leave to amend because there is no factual basis for their claim. Dkt. 40 at 12. They do concede, though, that Plaintiffs may still pursue their manufacturing defect claim if they obtain facts to support such a claim during discovery. *Id.* It is possible that Plaintiffs may be able to plausibly plead at this stage a manufacturing defect claim that specifies how their products were defective due to factory departure from proper specifications.

Therefore, the Court DECLINES to adopt the R&R as to this issue. Defendants' motion to dismiss is GRANTED, and Plaintiffs' claim for manufacturing defect is DISMISSED with leave to amend.

2. Breach of Express Warranty

Defendants additionally object to the R&R's conclusion that Plaintiffs adequately alleged a breach of express warranty claim. Dkt. 40 at 12–18. They argue that the R&R erred in concluding that the mesh implants' Instructions for Use ("IFUs") constituted an express warranty and that a medical device's warning label may not create an express warranty.

The WPLA provides for strict liability if a "claimant's harm was proximately cause by the fact that the product was . . . not reasonably safe because it did not conform

to the manufacturer's express warranty." RCW 7.72.030(2). Washington law defines an express warranty as "any affirmation of fact or promise." RCW 62A.2-313(a). To state a claim for breach of express warranty, a plaintiff must plausibly allege that (1) the warranty was made part of the basis of the bargain; (2) the warranty relates to a material fact concerning the product; and (3) the warranty turns out to be untrue. RCW 7.72.030(2)(b).

Defendants cite to, *inter alia*, *Bryant v. Wyeth*, 879 F. Supp. 2d 1214 (W.D. Wash. 2012), in support of their argument that a medical warning label cannot serve as an express warranty of the product's safety. In *Bryant*, the Court concluded that a prescription medication's warning label did not constitute an express warranty because the warning provided only general risk information, not a promise or factual representation. *Id.* at 1227. However, the Court reached this conclusion when deciding a motion for summary judgment—not a motion to dismiss. *See id.* at 1218. The Court must take the allegations as true, and Plaintiffs have alleged that the IFUs contained promises that the mesh implants were not subject to degradation or weakening. *See* Dkt. 29, ¶¶ 160–165. The Court agrees with the R&R's conclusion that "whether the Instructions for Use in fact contain such a claim and whether the context was such that it created an express warranty [are] issues not before the Court at this time." Dkt. 37 at 15.

Defendants additionally object to the fact that Plaintiffs did not attach the IFUs to their complaint. This issue was not raised before Judge Creatura, however. The Court declines to address this new argument because Plaintiffs have plausibly pled the express warranties contained within the IFUs. *See, e.g.*, Dkt. 29, ¶ 164; *see also Brown v. Roe*,

279 F.3d 742, 745–46 (9th Cir. 2002) (rejecting the Fourth Circuit's holding that a district court must consider new arguments raised for the first time in an objection to a magistrate judge's R&R); *United States v. Howell*, 231 F.3d 615, 622 (9th Cir. 2000) (district courts have discretion to consider new evidence raised for the first time in an objection to a magistrate judge's R&R); *Olmos v. Ryan*, No. CV-11-00344-PHX-GMS, 2013 WL 3199831, at *8 (D. Ariz. June 24, 2013) ("Generally, a district court need not consider new arguments raised for the first time in objections to an R & R.").

Defendants' remaining objections do not fare any better. Defendants again argue that Plaintiffs' allegations are not materially different than the allegations pled in *Hernandez v. Johnson & Johnson*, No. 4:20-cv-05136-SMJ, 2021 WL 320612 (E.D. Wash. Jan. 8, 2021), an Eastern District of Washington products liability case involving Defendants' mesh products. *Compare* Dkt. 30 at 13 *with* Dkt. 40 at 15. The R&R considered Defendants' arguments based on *Hernandez* and properly rejected those arguments. *See* Dkt. 37 at 16. Defendants' additional citations to non-binding case law are not persuasive—the Court agrees with the R&R's conclusion that Plaintiffs have adequately alleged a breach of express warranty claim at this stage.

The R&R is therefore ADOPTED as to this issue.

3. Common Law Fraud & Consumer Protection Act

Finally, Defendants object to the R&R's conclusion that Plaintiffs have adequately pled their fraud-based claims, including common law fraud and violations of the CPA (which sound in fraud). *See* Dkt. 40 at 18–21. While the R&R decided that Plaintiffs were not entitled to a lenient application of Rule 9(b) pursuant to *United States ex rel. Lee v.*

SmithKline Beecham, Inc., 245 F.3d 1048 (9th Cir. 2001), it did conclude that the Rule 9(b) standard is somewhat relaxed because Plaintiffs' fraud-based claims primarily sound in the omission of information. Dkt. 37 at 19–20. The R&R relied in part on *Falk v. General Motors Corporation*, 496 F. Supp. 2d 1088 (N.D. Cal. 2007), which held that "a plaintiff in a fraud by omission suit will not be able to specify the time, place, and specific content of an omission as precisely as would a plaintiff in a false representation claim," *id.* at 1098–99.

Defendants argue that "federal courts in Washington have not accepted the notion that Rule 9(b) should be relaxed in a fraudulent omission claim." Dkt. 40 at 19. Yet this Court has in fact cited *Falk* with approval and has concluded that a fraud by omission claim meets Rule 9(b)'s requirements when the claim is pled with particularity. *See, e.g.*, *Short v. Hyundai Motor Co.*, No. C19-0318 JLR, 2020 WL 6132214, at *5 (W.D. Wash. Oct. 19, 2020); *Floyd Blinksy Trucking, Inc. v. Navistar, Inc.*, No. C15-5467 BHS, 2020 WL 7043299, at *2 (W.D. Wash. Dec. 1, 2020). Upon a review of Plaintiffs' complaint, the Court agrees with the R&R that Plaintiffs' fraud-based claims are based on a theory that Defendants failed to disclose material information. *See, e.g.*, Dkt. 29, ¶ 194 ("Defendants had a duty to disclose and/or not conceal the true and material risks, adverse events, and contraindications of the TVT-S and Prosima products to Plaintiffs, their implanting medical providers, the medical community, the FDA, and/or the public at large."). The R&R, therefore, did not err in applying *Falk* to Plaintiffs' claims.

Defendants additionally argue that Plaintiffs' allegations are insufficient because they are not specific enough. It is true that this Court has dismissed fraud-based claims in

similar mesh product cases on motions for summary judgment for a failure to identify particular fraudulent statements relied upon; but those fraud claims were not fraud by omission claims. *See, e.g.*, *Ellis v. Ethicon, Inc.*, No. C20-5692 BHS, 2021 WL 2949779, at *5 (W.D. Wash. July 14, 2021). Here, as the R&R noted, it is difficult to allege the who, when, and where of the omissions.

Plaintiffs allege that Defendants were aware of the mesh products' issues but did not disclose the material information. *See, e.g.*, Dkt. 29, ¶ 199 ("Defendants knowingly, falsely, and actively misrepresented that the TVT-S and Prosima products did not cause chronic injuries, degrade, harden, shrink or contract, fray, cord, curl, lose particles, oxidize, corrode, and/or otherwise deform, with actual knowledge that these representations were false."). They have sufficiently alleged that Defendants knew that their mesh products were defective and failed to disclose this information to Plaintiffs' detriment. The non-binding case law Defendants cite in their objections does not convince the Court otherwise. The Court agrees with the R&R that Plaintiffs have adequately pleaded their claims sounding in fraud by omission to meet Rule 9(b).

The R&R is therefore ADOPTED as to this issue.

III. ORDER

The Court having considered the R&R, the parties' objections, and the remaining record, does hereby find and order as follows:

(1) The R&R is **ADOPTED in part**;

(2) Defendants' motion to dismiss, Dkt. 30, is **GRANTED in part** and **DENIED in part**;

(3) Plaintiffs' claim for unjust enrichment is **DISMISSED without leave to amend**;

(4) Plaintiffs' claims for manufacturing defect, constructive fraud, fraudulent inducement, and breach of the implied warranty of merchantability are **DISMISSED with leave to amend**;

(5) Plaintiffs are **GRANTED** leave to amend and shall file their amended complaint within 30 days of this Order; and

(6) This matter is re-referred to Judge Creatura for further proceedings.

Dated this 2nd day of September, 2021.

BENJAMIN H. SETTLE
United States District Judge